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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,584	08/30/2003	Vit Lauermann		8871

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EXAMINER	
KUDLA, JOSEPH S	
ART UNIT	**PAPER NUMBER**
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/651,584	LAUERMANN, VIT	
	Examiner	Art Unit	
	Joseph S. Kudla	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*. See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to an inhibitor which is deactivatable by a reagent produced by a target cell comprising a first moiety that binds, inhibits, suppresses, neutralizes, or decreases activity of a biologically active agent wherein said first moiety is operably linked to a second moiety specifically cleavable by a reagent produced by a target cell, wherein said first and second moieties are not attached in nature and wherein specific cleavage of said second moiety causes reduction of binding, inhibiting, suppressing, or neutralizing activity of said inhibitor, classified in class 514, subclass 1.

II. Claims 18-19, drawn to a method of site specific activation of an active agent comprising administration of an inhibitor which is deactivatable by a reagent produced by a target cell comprising a first moiety that binds, inhibits, suppresses, neutralizes, or decreases activity of a biologically active agent wherein said first moiety is operably linked to a second moiety specifically cleavable by a reagent produced by a target cell, wherein said first and second moieties are not attached in nature and

wherein specific cleavage of said second moiety causes, classified in class 424, subclass 178.1.

III. Claims 20-23, drawn to a method for treating a cancer cell comprising contacting the cell with an inhibitor which is deactivatable by a reagent produced by a target cell comprising a first moiety that binds, inhibits, suppresses, neutralizes, or decreases activity of a biologically active agent wherein said first moiety is operably linked to a second moiety specifically cleavable by a reagent produced by a target cell, wherein said first and second moieties are not attached in nature and wherein specific cleavage of said second moiety causes reduction of binding, inhibiting, suppressing, or neutralizing activity of said inhibitor and restoration of activity of said active agent; said inhibitor is administered alone or together with an active agent such that the activity of the active agent is reduced until it reaches a target cell producing a reagent wherein the inhibitor is cleaved by said reagent and activity of said active agent is restored, classified in class 514, subclass 964.

The inventions of the instant application are distinct from each other for the following reasons:

a. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process as claimed can be practiced with a materially different product, such as partial agonist.

b. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process as claimed can be practiced with a materially different product to treat cancer, such as radiation therapy.

c. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

2. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be

treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of Species

First Moiety

3. In the event Applicant elects any one of groups I to III, Claim 1 is generic due to a plurality of the following disclosed patentably distinct species represented in claims 2-3. The compounds of claims 2-3 encompass many different and distinct compositions. The compositions vary distinctly in their structures and functions. Thus, an individual search is required of each individual composition. Therefore, Applicant is required to

elect a specific compound, to which the elected invention will be examined on the merits as drawn to as well as identifying those claims to which the elected compound/invention is drawn.

Type of Inhibitor

4. In the event Applicant elects any one of groups I to III, Claim 1 is generic due to a plurality of the following disclosed patentably distinct species represented in claim 4. The inhibitors of claim 4 encompass many different and distinct inhibitors. The compositions vary distinctly in their structures and functions. Thus, an individual search is required of each individual composition. Therefore, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as drawn to as well as identifying those claims to which the elected compound/invention is drawn.

Biologically Active Ingredient

5. In the event Applicant elects any one of groups I to III, Claim 1 is generic due to a plurality of the following disclosed patentably distinct species represented in claim 5. The compounds of claim 5 encompass many different and distinct compositions. The compositions vary distinctly in their structures and functions. Thus, an individual search is required of each individual composition. Therefore, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as drawn to as well as identifying those claims to which the elected compound/invention is drawn.

Second Moiety

6. In the event Applicant elects any one of groups I to III, Claim 1 is generic due to a plurality of the following disclosed patentably distinct species represented in claims 8-10. The compounds of claims 8-10 encompass many different and distinct compositions. The compositions vary distinctly in their structures and functions. Thus, an individual search is required of each individual composition. Therefore, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as drawn to as well as identifying those claims to which the elected compound/invention is drawn.

Reagent

7. In the event Applicant elects any one of groups I to III, Claim 1 is generic due to a plurality of the following disclosed patentably distinct species represented in claims 11-12. The compounds of claims 11-12 encompass many different and distinct compositions. The compositions vary distinctly in their structures and functions. Thus, an individual search is required of each individual composition. Therefore, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as drawn to as well as identifying those claims to which the elected compound/invention is drawn.

Disorder/Condition

8. In the event Applicant elects Group III, Applicant is required to elect a disorder. Claim 20 is generic due to a plurality of the following disclosed patentably distinct species represented in claim 22. The disorders in the instant specification in claim 22 vary distinctly symptomatically. The symptoms associated with breast cancer would vary distinctly from the symptoms associated with squamous cell carcinoma.For example, breast cancer would have the symptoms of breast pain, a painful lump in the breast tissue, redness or swelling of the breast, etc.; whereas squamous cell carcinoma, the symptoms would be the presence of an ulceration, difficulty in swallowing, or asymptomatic depending on the location of the squamous cell carcinoma. Therefore, a subject that has one disease/condition like breast cancer would not necessarily have the other disease/condition like squamous cell carcinoma. Thus, an individual search is required of each individual distinct disorder or medical condition. Applicant is required to elect a disorder/condition from claim 22, to which the elected invention will be examined on the merits as drawn to; as well as identifying those claims to which the elected compound/invention is drawn.

Applicant is required, in reply to this action, to elect a single species/disorder/ condition to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JK

Phyllis Spivack
1/2/08

PHYLLIS SPIVACK
PRIMARY EXAMINER